

- disease and to a method for using said pharmaceutical composition, classified in class 424, subclass 277.1.
- IV. Claims 1-7, 9, 10, 19-21, 22, 23, and 32, drawn to a pharmaceutical composition comprising grp170 and an immunogenic polypeptide associated with infectious disease and to a method for using said pharmaceutical composition, classified in class 424, subclass 277.1.
- V. Claims 11-15 and 35, drawn to a pharmaceutical composition comprising an antigen presenting cell modified to present hsp110 and an immunogenic polypeptide associated with cancer and a method for using said pharmaceutical composition, classified in class 424, subclass 93.21.
- VI. Claims 11-15 and 35, insofar as the claims are drawn to a pharmaceutical composition comprising an antigen presenting cell modified to present grp170 and an immunogenic polypeptide associated with cancer and a method for using said pharmaceutical composition, classified in class 424, subclass 93.21.
- VII. Claims 24-26, insofar as the claims are drawn to a method for producing T cells directed against a tumor cell comprising contacting T cells with an antigen presenting cell modified by contact with hsp110 and an immunogenic polypeptide associated with the tumor cell and a T cell produced by said method, classified in class 435, subclass 373 and class 435, subclass 372.3, respectively.
- VIII. Claims 24-26, insofar as the claims are drawn to a method for producing T cells directed against a tumor cell comprising contacting T cells with an antigen presenting cell modified by contact with grp170 and an immunogenic polypeptide associated with the tumor cell and a T cell produced by said method, classified in class 435, subclass 373 and class 435, subclass 372.3, respectively.
- IX. Claims 27, 36, and 37, insofar as the claims are drawn to a method for killing or removing tumor cells comprising contacting a biological sample with a T cell produced by the method of claim 24, which comprises contacting T cells with an antigen presenting cell modified by contact with hsp110, classified in class 435, subclass 373.
- X. Claims 27, 36, and 37, insofar as the claims are drawn to a method for killing or removing tumor cells comprising contacting a biological sample with a T cell produced by the method of claim 24, which comprises contacting T cells with an antigen presenting cell modified by contact with grp170, classified in class 435, subclass 373.
- XI. Claims 28-30, insofar as the claims are drawn to a method for producing T cells directed against a M. tuberculosis-infected cell comprising contacting T cells with an antigen presenting cell modified by contact with hsp110 and an immunogenic polypeptide associated with the M. tuberculosis-infected cell and a T cell produced by said method, classified in class 435, subclass 373 and class 435, subclass 372.3, respectively.
- XII. Claims 28-30, insofar as the claims are drawn to a method for producing T cells directed against a M. tuberculosis-infected cell comprising contacting T cells with an

antigen presenting cell modified by contact with grp170 and an immunogenic polypeptide associated with the M. tuberculosis-infected cell and a T cell produced by said method, classified in class 435, subclass 373 and class 435, subclass 372.3, respectively.

- XIII. Claim 31, drawn to a method for killing a M. tuberculosis-infected cell comprising contacting the cell with a T cell produced by the method of claim 28, which comprises contacting T cells with an antigen presenting cell modified by contact with hsp110, classified in class 435, subclass 373.
- XIV. Claim 31, drawn to a method for killing a M. tuberculosis-infected cell comprising contacting the cell with a T cell produced by the method of claim 28, which comprises contacting T cells with an antigen presenting cell modified by contact with grp170, classified in class 435, subclass 373.
- XV. Claims 38 and 39, insofar as the method for inhibiting tumor growth in a subject comprising incubating T cells with an antigen presenting cell modified to present hsp110 and an immunogenic polypeptide associated with the tumor, classified in class 424, subclass 93.1.
- XVI. Claims 38 and 39, insofar as the method for inhibiting tumor growth in a subject comprising incubating T cells with an antigen presenting cell modified to present grp170 and an immunogenic polypeptide associated with the tumor; classified in class 424, subclass 93.1.
- XVII. Claims 40-42, insofar as the claims are drawn to a method for enhancing an immune response to an antigen in a subject comprising administering hsp110 to the subject, classified in class 424, subclass 278.1.
- XVIII. Claims 40-42, insofar as the claims are drawn to a method for enhancing an immune response to an antigen in a subject comprising administering grp170 to the subject, classified in class 424, subclass 278.1.
- XIX. Claims 43-45, insofar as the claims are drawn to a method for enhancing the immunogenicity of a stress protein complex comprising hsp110, classified in class 424, subclass 278.1.
- XX. Claims 43-45, insofar as the claims are drawn to a method for enhancing the immunogenicity of a stress protein complex comprising grp170, classified in class 514, subclass 12.

In addition, the Examiner is requiring election of species within generic claim 7 as follows:

- (A) hsp70,
- (B) hsp 90,
- (C) grp78 or
- (D) grp94.

The Examiner further is requiring election of species within generic claim 8 as follows:

(A) hsp70 or

(B) hsp25.

The Examiner is requiring yet further election of species within generic claim 21 as follows:

(A) Mtb8.4 or

(B) Mtb39.

In response, Applicants elect group I, namely claims 1-10, 16-18, 22, 23, 33 and 34, with traverse. Applicants respectfully disagree with the assertion by the Office that the 20 claim groups involve separate and distinct inventions.

35 U.S.C. §121 provides that "If two or more independent and distinct inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions." M.P.E.P. §802.01 deviates from the plain meaning of "independent and distinct" by interpreting "and" to mean "or". The Patent Office relies on the absence from the legislative history of anything contrary to this interpretation as support for their position that "and" means "or". Applicants respectfully note that this position is contrary to the rules of statutory construction. Restriction between two dependent inventions is not permissible under the plain meaning of 35 U.S.C. §121.

The Examiner does not assert that the inventions of the 20 claim groups are independent, but rather that the inventions of the 20 claim groups are distinct because they are directed to products that are biologically and chemically distinct, unrelated in structure and/or function, and/or made by and/or used in different methods; materially different methods that differ at least in objectives, method steps, reagents and/or doses and/or schedules used, response variables, assays for end products and/or results, and criteria for success; a product and processes of making and using the product; or not specifically used in any of the steps of claimed methods. Applicants assert that restriction is improper because the claimed subject matter is dependent and closely related.

Applicants further urge the Examiner take into consideration that the subject matter of each of the claim groups is linked by a common inventive concept, namely the pharmaceutically-relevant use of a stress protein complexed with an immunogenic polypeptide.

According to M.P.E.P. §803, there are two criteria for a proper restriction requirement. First, the two inventions must be independent and distinct. In addition, there must be a serious burden on the Examiner if restriction is not required. Even if the first criterion has been met in the present case, which it has not, the second criterion has not been met.

Applicants assert that a search into prior art with regard to the invention of the different groups is so related that separate significant search efforts should not be necessary. At the very least, Applicants maintain that the subject matter of groups I, III, V, VII, IX, XI, XIII, XV and XVII is dependent and related to the common inventive concept of using hsp110 complexed to an immunogenic polypeptide to achieve an enhanced immune response to the polypeptide, such that examination of these groups can be accomplished with a single search effort. Accordingly, there is no serious burden on the Examiner to collectively examine the different claim groups of the subject application, and restriction is not proper under M.P.E.P. §803.

Consequently, Applicants respectfully request the Examiner reconsider and withdraw the restriction requirement. It is also submitted that this application is now in good order for allowance and such allowance is respectfully solicited. Should the Examiner believe minor matters remain that can be resolved by telephone, the Examiner is urged to call Applicants' undersigned attorney.

Respectfully submitted,

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